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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,402	05/30/2001	Kevin Morton	NEOMTRX.004A	7475

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,402	MORTON, KEVIN	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,35,40-42 and 48-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,35,40-42,48-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's Request for Continued Examination has been received and entered into the case. Claims 1 – 32, 36 – 39 and 43 – 47 have been canceled; claims 62 – 67 have been added. Claims 33, 35, 40 – 42 and 48 – 67 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 33, 35, 40 – 42 and 48 – 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 33 recites functional limitations of the sample collector in lines 16 – 18 which was not described in the specification as originally filed. In addition, new claims 62 – 67 also recite limitations not described in the specification as originally filed. As such, the limitations and claims are rejected as containing new matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 33, 35, 40 – 42 and 48 – 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and its dependents are rendered vague and indefinite because the method is recited as a method of screening for breast cancer marker, however the method steps only recite limitations to the method of collecting intraductal fluid. Moreover, the claims fail to recite any steps to the method of screening, other than "screening the removed carrier fluid". It is unclear how one would practice the claimed method of screening for a breast cancer marker, by screening for a breast cancer marker.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 33, 35, 40 – 42 and 48 – 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hung '228 in view of Hung '7115 and/or Nguyen and further in view of Covington.

Applicant claims a method of screening for a breast cancer marker in a patient, the method comprising providing a patient with at least one breast duct having an external opening, directing a stream of carrier fluid under pressure into the opening, directing a carrier fluid under

pressure into the opening, removing the carrier fluid through the opening by applying compression, suction and heat to the breast with a claimed device, followed by screening the removed fluid for at least one breast cancer marker. The screening step comprises screening for cytologically abnormal cells, the breast cancer marker is associated with at least one condition selected from tumorigenesis, tumor growth, neovascularization, and cancer invasion. The method further comprises manipulating the duct to enhance transport of carrier fluid, the compressive force is peristaltic, the fluid is introduced transductally or percutaneously, and the fluid comprises a component for enhancing marker transport. The removing step occurs immediately after carrier introduction, or alternatively after a sufficient indwelling period. The carrier comprises an aqueous solution, and the breast marker is a metabolite, carcinoma cell, dysplastic cell, or is selected from a protein, peptide, glycoprotein, lipid, glycolipid or proteolipid. The removins step is performed by contacting the breast with a device comprising specifically identified attributes in claims 33, 48 – 52 and 62 – 67.

Hung '228 teaches methods for collecting breast ductal fluid comprising cellular material and markers (disease markers) to identify breast precancer or cancer in patients (abstract). Hung '228 teaches the method wherein a wash fluid (carrier fluid) is introduced into the breast duct for 1 second to 1 hour, followed by removal via massage and aspiration (or suction) (col.11 line 45 – col.13 line 45). The cellular material is then cytologically screened for cell conditions and other disease markers such as proteins, peptides, lipids, glycoproteins metabolites (col.4), chromosomal abnormalities, carcinoma, atypical hyperplasias, and/or growth factors (col. 12 – 15). The carrier fluid may further contain components for enhancing fluid removal (col.12)

Hung '228 does not teach the method wherein heat is applied to the breast. However, Hung '7115 teaches methods of nipple aspiration wherein fluid yield is increased by applying compression, suction, and heat (0015). In addition, Nguyen teaches applying a warm compress to the breast to facilitate breast fluid removal (0023). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Hung '7115 and/or Nguyen to apply heat to the breast in the methods of Hung '228 with a reasonable expectation for successfully obtaining breast fluid for screening. Although Hung '228 does not teach each of the specific modes of compression or disease markers, it would have been well within the purview of one of ordinary skill in the art to optimize such markers and pressure techniques as a matter of routine experimentation.

The above references do not teach using the claimed device. However, Covington teaches the claimed device for removing breast fluid (claims, col.3-4). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Covington to practice the methods of Hung '228 and Hung '7115/Nguyen with the claimed device as the device is disclosed effective for removing breast ductal fluid. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to practice the methods of Hung '228 and Hung '7115/Nguyen with the device of Covington with a reasonable expectation for successfully obtaining breast duct fluid and screening for breast cancer. Although Covington does not specifically teach the functions limitations of the sample collector in claims 33 and 62 – 67, the devices are the same. Therefore such functions would have intrinsically been part of the device of Covington.

7. Claims 33, 35, 40 – 42 and 48 – 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love in view of Hung '7115 and Nguyen and further in view of Covington.

Applicant claims a method of screening for a breast cancer marker in a patient, the method comprising providing a patient with at least one breast duct having an external opening, directing a stream of carrier fluid under pressure into the opening, directing a carrier fluid under pressure into the opening, removing the carrier fluid through the opening by applying compression, suction and heat to the breast with a claimed device, followed by screening the removed fluid for at least one breast cancer marker. The screening step comprises screening for cytologically abnormal cells, the breast cancer marker is associated with at least one condition selected from tumorigenesis, tumor growth, neovascularization, and cancer invasion. The method further comprises manipulating the duct to enhance transport of carrier fluid, the compressive force is peristaltic, the fluid is introduced transductally or percutaneously, and the fluid comprises a component for enhancing marker transport. The removing step occurs immediately after carrier introduction, or alternatively after a sufficient indwelling period. The carrier comprises an aqueous solution, and the breast marker is a metabolite, carcinoma cell, dysplastic cell, or is selected from a protein, peptide, glycoprotein, lipid, glycolipid or proteolipid. The removins step is performed by contacting the breast with a device comprising specifically identified attributes in claims 33, 48 – 52 and 62 – 67.

Love teaches methods for obtaining cellular material from breast ducts (abstract) for screening, diagnosing and monitoring disease states, cancer and pre cancerous conditions (col.3 line 5-20). Specifically, the method comprises introducing a wash fluid (carrier fluid) into a breast ductal orifice (external opening) for 1 – 5 minutes, collecting (removing) the fluid and

screening the material for proteins, carbohydrates (lipids, peptides) cellular markers, morphological, histochemical and/or immunohistochemical abnormalities to determine the presence of cancer or pre-cancerous conditions (physiological conditions) (col.3-4).

Love does not teach the method wherein heat and suction is applied to the breast, or wherein additional components are added to enhance fluid transport. However, Hung '7115 teaches methods of nipple aspiration wherein fluid yield is increased by applying compression, suction, and heat (0015). In addition, Nguyen teaches applying a warm compress to the breast as well as drugs to facilitate breast fluid removal (0023). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Hung '7115 and/or Nguyen to apply heat to the breast in the methods of Love with a reasonable expectation for successfully obtaining breast fluid for screening. Although Love does not teach each of the specific modes of compression or disease markers, it would have been well within the purview of one of ordinary skill in the art to optimize such markers and pressure techniques as a matter of routine experimentation.

The above references do not teach using the claimed device. However, Covington teaches the claimed device for removing breast fluid (claims, col.3-4). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Covington to practice the methods of Love and Hung '7115/Nguyen with the claimed device as the device is disclosed effective for removing breast ductal fluid. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to practice the methods of Love and Hung '7115/Nguyen with the device of Covington with a reasonable expectation for successfully obtaining breast duct fluid and screening for breast cancer. Although Covington

does not specifically teach the functions limitations of the sample collector in claims 33 and 62 – 67, the devices are the same. Therefore such functions would have intrinsically been part of the device of Covington.

8. Claims 33, 35, 40 – 42 and 48 – 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hung '228 or Love in view of Covington.

Applicant claims a method of screening for a breast cancer marker in a patient, the method comprising providing a patient with at least one breast duct having an external opening, directing a stream of carrier fluid under pressure into the opening, directing a carrier fluid under pressure into the opening, removing the carrier fluid through the opening by applying compression, suction and heat to the breast with a claimed device, followed by screening the removed fluid for at least one breast cancer marker. The screening step comprises screening for cytologically abnormal cells, the breast cancer marker is associated with at least one condition selected from tumorigenesis, tumor growth, neovascularization, and cancer invasion. The method further comprises manipulating the duct to enhance transport of carrier fluid, the compressive force is peristaltic, the fluid is introduced transductally or percutaneously, and the fluid comprises a component for enhancing marker transport. The removing step occurs immediately after carrier introduction, or alternatively after a sufficient indwelling period. The carrier comprises an aqueous solution, and the breast marker is a metabolite, carcinoma cell, dysplastic cell, or is selected from a protein, peptide, glycoprotein, lipid, glycolipid or proteolipid. The removins step is performed by contacting the breast with a device comprising specifically identified attributes in claims 33, 48 – 52 and 62 – 67.

Hung '228 teaches methods for collecting breast ductal fluid comprising cellular material and markers (disease markers) to identify breast precancer or cancer in patients (abstract). Hung '228 teaches the method wherein a wash fluid (carrier fluid) is introduced into the breast duct for 1 second to 1 hour, followed by removal via massage and aspiration (or suction) (col.11 line 45 – col.13 line 45). The cellular material is then cytologically screened for cell conditions and other disease markers such as proteins, peptides, lipids, glycoproteins metabolites (col.4), chromosomal abnormalities, carcinoma, atypical hyperplasias, and/or growth factors (col. 12 – 15). The carrier fluid may further contain components for enhancing fluid removal (col.12)

Love teaches methods for obtaining cellular material from breast ducts (abstract) for screening, diagnosing and monitoring disease states, cancer and pre cancerous conditions (col.3 line 5-20). Specifically, the method comprises introducing a wash fluid (carrier fluid) into a breast ductal orifice (external opening) for 1 – 5 minutes, collecting (removing) the fluid and screening the material for proteins, carbohydrates (lipids, peptides) cellular markers, morphological, histochemical and/or immunohistochemical abnormalities to determine the presence of cancer or pre-cancerous conditions (physiological conditions) (col.3-4).

The above references do not teach using the claimed device. However, Covington teaches the claimed device for removing breast fluid (claims, col.3-4). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Covington to practice the methods of Hung '228 or Love with the claimed device as the device is disclosed effective for removing breast ductal fluid. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to practice the methods of Hung '228 or Love with the device of Covington with a reasonable expectation for successfully obtaining

breast duct fluid and screening for breast cancer. Although Covington does not specifically teach the functions limitations of the sample collector in claims 33 and 62 – 67, the devices are the same. Therefore such functions would have intrinsically been part of the device of Covington.

Applicant argues that the references do not teach the device with the claimed functional limitations recited in claim 1 and 62 – 67. However, as stated above, the device claimed and that of Covington are the same. Therefore such functions must intrinsically be present in the device of Covington.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Effective January 20, 2004, any inquires should be made to Ruth Davis whose telephone number is 571-272-0915. The examiner's supervisor, Michael Wityshyn, can be reached at 571-272-0926.

Ruth A. Davis; rad
December 19, 2003.

LEON B. LANKFORD, JR.
PRIMARY EXAMINER